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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/694,448	10/27/2003	Kathleen C.M. Campbell	SIU 7398	8896

321 7590 10/01/2004

SENNIGER POWERS LEAVITT AND ROEDEL  
 ONE METROPOLITAN SQUARE  
 16TH FLOOR  
 ST LOUIS, MO 63102

EXAMINER
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COOK, REBECCA

ART UNIT	PAPER NUMBER
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1614

DATE MAILED: 10/01/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

**Application No.**

10/694,448

**Applicant(s)**

CAMPBELL, KATHLEEN C.M.

**Examiner**

Rebecca Cook

**Art Unit**

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
  - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
  - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
  - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 27 October 2003.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-45 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-45 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 27 October 2003 is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All   b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>1/16/04</u> . | 6) <input type="checkbox"/> Other: _____  |

### DETAILED ACTION

The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed.

#### ***Claim Rejections - 35 USC § 112***

Claims 1, 7-30, 33, 37-45 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. It is not clear what compounds are included in the phrase "methionine-like moiety." Is it intended to include compounds having heterocyclic substituents, for example.

Claims 1-45 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for D-Met to reducing the incidence of CDDP-induced ototoxicity, does not reasonably provide enablement for the method as recited in claims 1, 31 and 33. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims. On pages 5-6 the specification discloses that not all sulfur-containing compounds provide protection against all of CDDP's toxicities and it is not possible to predict which protective agents will be effective or ineffective for this purpose. It goes on to say that sulfur-containing compounds protective against one type of CDDP toxicity frequently do not protect against other CDDP toxicities, and it is not possible to predict the specific antitoxic effectiveness of such compounds. In

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addition, even among agents that provide CDDP otoprotection, the protection may be so inconsistent and/or the side effects so great that they would not be used clinically.

Furthermore, while the data for CDDP demonstrates a reduction in ototoxicity, other than the use of vaccines to prevent some infections and gene therapy, there are no compounds in medical science today that can "prevent" any conditions.

Claims 1-45 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In the independent claims it is not clear that the ototoxicity is caused by the anti-tumor platinum coordination compound or the aminoglycoside antibiotic.

There is no antecedent basis in claim 31 for the recitation "said noise exposure" in claim 32.

### ***Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-45 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-36 of U.S. Patent No. 6,187,817. Although the conflicting claims are not identical, they are not patentably distinct from each other because the D-methionine of '817 would be included in the "methionine-like" and sulfur containing compounds of the instant claims.

Claims 1-45 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-25 of U.S. Patent No. 6,265,386. Although the conflicting claims are not identical, they are not patentably distinct from each other because the D-methionine of '386 would be included in the "methionine-like" and sulfur containing compounds of the instant claims.

Claims 1-45 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-45 of copending Application No. 10/694,432. Although the conflicting claims are not identical, they are not patentably distinct from each other because the "comprising" language of '432 would allow for the instant anti-tumor platinum-coordination compound, which is a well-known agent in the treatment of cancer, and the instant "comprising" language would allow for the radiation of '448.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

#### ***Information Disclosure Statement***

References 8-75 could not be considered since they were not available in the parent files.

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### Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Cook whose telephone number is (571) 272-0571. The examiner can normally be reached on Monday through Thursday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low, can be reached on (571) 272-0951.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to Renee Jones (571) 272-0547 in Customer Service.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

The official fax number is 703-872-9806

Rebecca Cook



Primary Examiner  
Art Unit 1614

September 29, 2004